UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HELEN MCLAUGHLIN,	:	Case No. 14-cv-7315	
Plaintiff,	:	The Hon. John R. Padova	
v.	:	NO. 14-7316 (Ruble)	NO. 16-3732 (Gross)
	:	NO. 14-7317 (Strimel)	NO. 16-3733 (Johnson)
BAYER ESSURE INC. et al.,	:	NO. 14-7318 (Stelzer)	NO. 16-3766 (Summerlin)
	:	NO. 15-0384 (Walsh)	NO. 16-3767 (Rodvill)
Defendants.	:	NO. 16-1458 (Dunstan)	NO. 16-3768 (Catanzano)
	:	NO. 16-1645 (Clarke)	NO. 16-3769 (Aponte)
And Related Actions	:	NO. 16-1921 (Souto)	NO. 16-4081 (Bradford)
	:	NO. 16-2166 (B. Bailey)	NO. 17-2915 (Wistrom)
	:	NO. 16-2154 (Campos)	NO. 17-3968 (Bobo)
	:	NO. 16-2717 (Bolds)	NO. 17-4417 (Guess)
	:	NO. 16-3049 (Tulgetske)	NO. 17-4936 (Gonzalez)
	:	NO. 16-3409 (Abbey)	NO. 18-0037 (Jenson)
	:	NO. 16-3589 (Burgis)	NO. 18-0836 (Morgan)
	:	NO. 16-3710 (Dong)	NO. 18-0837 (Galan)
	:	NO. 16-3730 (Mantor)	No. 18-0838 (Alfaro)
	:	NO. 16-3731 (Olague)	NO. 18-908 (Archer)

PLAINTIFFS' SURREPLY IN OPPOSITION TO MOTION FOR PARTIAL SUMMARY JUDGMENT

On a motion for summary judgment, the moving party bears the initial burden of informing the Court of the bases for the motion, and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact.[1] Defendants' Motion for Partial Summary Judgment argues that exemplar Plaintiffs' claims are time barred by the applicable statute of limitations, but they have failed to inform the Court of the basis for this motion with regard to *each cause of action* (failure to warn, negligent training, negligent risk management, negligent misrepresentation, breach of warranty) and *as to each compensable injury*. Although Defendants' motion is captioned a motion for *partial* summary judgment, it is not at all clear to which causes of action and to which injuries it was intended to apply, and to which it was not. Defendants have failed to identify the bases of the motion, and their motion should therefore be denied for failing to meet their burden.

Although Plaintiffs were disadvantaged by the imprecision of Defendants' motion, Plaintiffs have read the motion as applying to their tort claims, but not their breach of warranty claims,[2] and to the injuries identified in the Motion, and have responded accordingly. Guided by this reading of the motion, the exemplar Plaintiffs have put forth sufficient evidence to create a genuine issue of material fact as to whether the discovery rule tolls the statute of limitations regarding their tort claims. Accordingly, they ask the Court to deny Defendants' Motion for Partial Summary Judgment.

In the alternative, Plaintiffs seek discovery on the equitable tolling doctrine of fraudulent concealment.

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[1] *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Wawrzynek v. Statprobe, Inc.*, 2007 U.S. Dist. LEXIS 80155.

[2] Defendants' Motion and Reply make no mention of Plaintiffs' breach of warranty claims, and they do not set forth or analyze Pennsylvania law on the statute of limitations for breach of warranty claims. See also FN 54, *infra*.

I. Plaintiffs Do Not Misstate or Misapply Pennsylvania Law Regarding the Discovery Rule

Under Pennsylvania, a statute of limitations does not begin to accrue until the "injured party possesses *sufficient critical facts* to put him on notice"[3] that he has been injured, *and* that "his injury has been *caused by another party's conduct*."[4] Under both the Pennsylvania Suggested Standard Civil Jury Instruction Section 18.01 and the Pennsylvania Supreme Court's decision in *Wilson v. El-Daief*,[5] the statute of limitations begins to run when a plaintiff has "actual or constructive knowledge of at least some form of significant harm and of a *factual cause* linked to another's conduct."[6] Defendants specifically pointed to this language in their reply brief and emphasized the words: *factual causation*. The law is clear: it is not just knowledge that an injury occurred that triggers the statute of limitations, but knowledge of a *factual cause* of that injury.[7] If there is an issue of fact as to when Plaintiffs knew, or could have known, the factual cause of their injury, summary judgment should be denied.

This issue is at the heart of the Plaintiffs' opposition brief and the reason the exemplar Plaintiffs attached declarations to that brief. It is, and always has been, the contention of the Plaintiffs in this litigation that the *factual cause* of their injuries has remained elusive precisely because the Defendants have denied that the Plaintiffs' injuries could be caused by the Essure device, or have at least significantly downplayed the risk.[8] Because of this, the exemplar Plaintiffs' doctors failed to identify the Essure device as the cause of their injuries,[9] and for

[3] *Lujan v. Mansmann*, No. 96-5098, 1997 U.S. Dist. LEXIS 14987, at * 10 (E.D. Pa. Sept. 24, 1997) (emphasis added).
[4] *Id.* at *11.
[5] *Wilson v. El-Daief*, 964 A.2d 354 (Pa. 2009).
[6] *Id.* 363-64.
[7] *Id.*
[8] See pages 11-15, *infra*.
[9] Plaintiffs are not expected to know more than their doctors about the medical causes of their injuries, where their doctors did not know that causation was probable, a reasonable jury could find that the Plaintiff was not on notice of the cause of her injuries. *Wilson*, 964 A.2d at 365; *Bohus v. Beloff*, 950 F.2d 919, 929-30 (3d Cir. 1991).

many years, the exemplar Plaintiffs could not determine, despite the exercise of reasonable diligence, that Essure was the factual cause of their injuries. Those Plaintiffs who expressed to their doctors a concern that their injuries might be Essure related had their suspicions unequivocally contradicted. These women simply could not acquire "sufficient critical facts" about the true risks posed by Essure. However, each of the exemplar Plaintiffs filed suit within the two-year statutory filing period once she came to possess sufficient critical facts to put her on notice that Essure was the factual cause of her injuries.

While Defendants are correct in stating that the statute of limitations may begin to run before a plaintiff learns that the conduct which caused their injury is *tortious*, the law is clear that plaintiffs must have learned (or been able to learn with the exercise of reasonable diligence) that a party's *conduct* was a probable cause of her injury. *Hayward v. Medical Center of Beaver County* provides a guide to understanding this principle.[10] In *Hayward*, a medical malpractice action, the plaintiff filed suit against two doctors more than two years after the alleged malpractice occurred. Believing the plaintiff had lung cancer, the doctors removed part of his lung. Both the doctors and the plaintiff learned shortly thereafter that the mass was a blood clot and not a tumor. The doctors told the plaintiff that the surgery was still necessary, although the mass was not a tumor. The plaintiff thereafter suffered progressive shortness of breath and difficulty breathing. The doctors told him this was normal and expected due to the removal of part of his lung. He consulted with a lung specialist and was told that symptoms were the result of the removal of a portion of his lung, but was not told that the surgery had been unnecessary. Finally, three years after the surgery, another doctor told him that the surgery had been unnecessary. Hayward argued that the statute of limitations should be tolled until the date of that discussion, because he could not be expected to know, before meeting with that doctor, that the

[10] *Hayward v. Medical Center of Beaver County*, 608 A.2d 1040 (Pa. 1992).

injury he suffered was "a result of *wrongdoing* and *not merely the unexpected, inevitable, or unforeseeable consequences of the medical treatment,* and therefore he acted reasonably in relying on his doctor's assurance that the surgery was medically necessary."[11] The Pennsylvania Supreme Court held that a jury could find that appellant acted reasonably, and as reasonable minds could differ as to when the cause of the injury was reasonably ascertainable, a jury question was presented and summary judgment was not appropriate.[12]

As in *Hayward*, the exemplar Plaintiffs have put forth factual evidence demonstrating that they exercised reasonable diligence, as well as factual evidence demonstrating why they could not reasonably ascertain that the injuries they suffered were factually caused by Essure, or Bayer's conduct, at the time their injury occurred. Where Defendants dispute whether an exemplar Plaintiff's actions, as described in her declaration, constitute reasonable diligence, unless reasonable minds could not differ on this issue, it is a question of fact which must go to a jury. Similarly, whether a plaintiff was or should have been on notice of the factual cause of her injury at an earlier point in time is "generally an issue for the jury unless the undisputed facts lead unerringly to the conclusion that the time it took to discover the injury was unreasonable as a matter of law."[13] The point at which the plaintiff should have known she suffered an injury and its cause remains a jury question, and "only where the facts are so clear that reasonable minds cannot differ may the commencement of the limitations period be determined as a matter of law."[14]

[11] *Id.* at 1043 (emphasis added).
[12] *Id.*
[13] *Lujan*, 1997 U.S. Dist. LEXIS 14987, *15.
[14] *Id.*

While the Plaintiffs bear the burden of proof on the discovery rule, just as they ultimately bear the burden of proof on the merits of each case, at this stage in the litigation, they need only demonstrate that there are genuine issues of material fact as to whether the discovery rule applies to toll the statute of limitations. They have put forth sufficient evidence to do so. Defendants challenge Plaintiffs' evidence in their Reply by raising credibility issues, and asking the Court to draw inferences and decide factual disputes which, under Pennsylvania law, must be decided by the jury. They do not point to any undisputed evidence which allows the Court to decide that the claims are time barred as a matter of law. Therefore, the Motion for Partial Summary Judgment must be denied.

Factual Disputes Regarding The Application Of Tolling Principles To Exemplar Plaintiffs

Plaintiffs will not reiterate the factual evidence set forth in their Statement of Material Facts and discussed in their Response to Defendants' Motion, except as necessary to address certain arguments made by Defendants in their Reply.

Explant Cases: Frye, Chandler, Carpenter

In an Essure case before a federal court in Kentucky, Judge Caldwell recently held that removal of the Essure device does not trigger the statute of limitations as a matter of law.[15] The 11th Circuit also recently held that explant of a medical device does not, as a matter of law, trigger the statute of limitations.[16] In that case, the plaintiff experienced problems with a vaginal mesh product, ObTape, and had it explanted in 2006, but did not suspect that ObTape was defective or that a defect in her implant had caused her injuries until she saw a commercial for ObTape litigation in 2013 which reported the existence of vaginal sling defects.[17] The district

[15] *Newsome v. Bayer Corp.*, 2018 WL 1906103, at *7 (E.D. Ky. Apr. 23, 2018).
[16] *Perryman v. Mentor Worldwide LLC*, No. 16-16645, Opinion dated August 28, 2018 (11th Circuit) (See Attachment A).
[17] *Perryman*, at pp. 4-6.

court granted summary judgment, holding that the plaintiff's claims were time barred. The Eleventh Circuit Court of Appeals reversed, finding that the symptoms the plaintiff experienced after implant of the mesh product were acknowledged side effects of the mesh and did not necessarily put her on notice that the mesh was defective.[18] The Eleventh Circuit thus concluded that when the plaintiff's claim accrued was an issue of fact for the jury.[19]

With regard to Ms. Frye and Ms. Chandler, who both believed at the time of explant that the factual cause of their injuries was likely their doctors' improper insertion of the Essure device,[20] it is for a jury to decide whether the facts surrounding their Essure explant surgery would have "awakened inquiry" regarding Bayer's role in causing their injuries, for a reasonable person with the information available to Plaintiffs at the time (as Defendants argue), or whether the duty of diligence was awakened and the statute of limitations began to run at some later time when new information about Bayer's role in causation became available (as Plaintiffs argue).[21]

Regarding Ms. Carpenter, it is for a jury to determine whether Ms. Carpenter's desire to have Essure removed (in part to restore her fertility)[22] indicated that she had knowledge (including sufficient critical facts) that Bayer's conduct was a factual cause of her injuries, when her doctor was attributing her symptoms to cysts and merely agreed to explant Essure while performing surgery to treat the cysts.[23] Moreover, a reasonable jury could find that any personal

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[18] *Id., at pp. 11-12.*
[19] *Id., at p. 12.*
[20] PSMF Ex. 2, Frye Decl. at ¶ 8; PSMF Ex. 3, Chandler Decl. at ¶ 10. Although Defendants argue that statements made to Plaintiffs by their family members about what they saw or what doctors told them about the Essure insertion procedure are hearsay, these statements are not offered for the truth of the matter asserted in those statements, but rather to show the basis for Plaintiffs' beliefs about the cause of their injuries. Therefore, they are not inadmissible hearsay.
[21] *See, In re Prempro Products Liability Litigation*, 586 F. 3d 547, 564 (8th Cir. 2009), discussed at pages 12-13, *infra.*
[22] While ultimately Ms. Carpenter, upon advice of her doctor, opted for a procedure which did not restore her fertility, her testimony is that restoration of her fertility was initially one of her goals in requesting removal, and her medical records are consistent with her declaration on these points. It is for a jury to decide what, if anything, to make of these facts. See PSMF Ex. 17, Carpenter Decl. at ¶ 9; PSMF Ex. 22.
[23] PSMF Ex. 17, Carpenter Decl. at ¶ 9; PSMF Ex. 22.

suspicions she held about an association between Essure and her symptoms, for which she had no medical or scientific support at the time of explant, did not trigger the statute of limitations because she had not yet acquired sufficient critical facts to draw a conclusion regarding *factual causation*.

Similarly, whether each of these three women was reasonably diligent in their efforts to determine the cause of their injuries after their explant surgery is for the jury. A reasonable jury might find that the factual cause of their injuries was not readily discoverable at the time of explant, or for years after the procedure, even with exercise of reasonable diligence, and that the women did exercise reasonable diligence once alerted to the possible link between Essure and their injuries by lawyer advertising or through other means.

Plaintiffs with Divisible Injuries: Colding, Thigpen, Moxley

Defendants' motion failed to identify all compensable injuries each woman suffered, much less demonstrate that there are no issues of fact as to whether the statute of limitations began to run on all injuries at the time of the first injury. Many Plaintiffs have identified multiple compensable injuries, some of which were unrelated, occurring at different times or resulting from different Essure coils.[24] For example, knowing that the right Essure coil was expelled, allowing fertilization and pregnancy to occur, would not start the statute of limitations on severe and persistent pain or autoimmune symptoms which arose due to a perforation of the uterus by the left coil, a separate injury with a distinct cause.

With regard to Ms. Colding, Defendants' Reply completely misrepresents the facts Ms. Colding set forth in her declaration. Ms. Colding learned that her *right* Essure coil had perforated her bowel in 2007, during a tubal ligation procedure deemed necessary to achieve sterilization

[24] Essure is somewhat unique among implanted medical devices, in that there are two Essure coils, each implanted in a separate fallopian tube.

when her right Essure coil could not be seen during the HSG confirmation test. The surgeon removed most of the right coil from her body.[25] The doctor confirmed that her left Essure coil was properly situated and it was not removed.[26] Despite medical treatment for ongoing abdominal and pelvic pain, migraines, and other symptoms after surgery to explant her right coil, it was not until 2016 that her doctors discovered that her left Essure device was protruding into her endometrial cavity, and only then did her doctors attribute her ongoing pain and other symptoms to the Essure device (specifically the left coil).[27] As these symptoms arose from a separate, unrelated compensable injury which was not identified by her physician until 2016, a reasonable jury could find that her complaint is not time barred as to the injuries arising from the left Essure coil. To the extent that Defendants argue that the Essure label was sufficient to put Plaintiff on notice of the cause of her persistent pain and other symptoms, this argument is addressed below.[28]

Two other exemplar Plaintiffs, Ms. Thigpen and Ms. Moxley, also suffered two unrelated injuries: pregnancy *and* severe and persistent pain. Even if the Court held that diagnosis of an unintended pregnancy immediately put a Plaintiff on notice that the Essure device had failed, and that Defendants' conduct was the factual cause of that injury (and Plaintiffs do not concede that this is the correct analysis, for the reasons set forth in the Response, as there are questions of fact for the jury as to what they understood about the factual cause of their injury), that would not constitute notice that Bayer's conduct was also the factual cause of her severe and persistent pain, in the absence of a medical opinion or other evidence connecting those symptoms to

[25] PSMF Ex. 1, Colding Decl. at ¶ 4.
[26] *Id.*
[27] *Id.* at ¶¶ 5-6.
[28] See pages 11-15, *infra.*

Essure.[29] Thus, the analysis below regarding temporal association and the adequacy of the label also apply to Ms. Thigpen and Ms. Moxley's allegations of severe and persistent pain.

Temporal Association Between Essure and Symptoms (Harvey, Wellington, Thigpen, Moxley)

For Plaintiffs who began suffering excessive bleeding, severe and persistent pain, and other symptoms shortly after Essure was implanted (e.g. Ms. Harvey, Ms. Wellington, Ms. Thigpen), it is for the jury to decide whether the mere temporal relationship between the insertion of the device and the onset of those symptoms was sufficient to trigger the statute of limitations. Plaintiffs raised a genuine issue of material fact as to whether this is a "common sense" conclusion, as Defendants argue, by pointing to evidence that they consulted their doctors about these symptoms, and despite the temporal association, their doctors did not conclude that Essure was the factual cause of their symptoms. The Third Circuit holds that lay persons should not be charged with greater knowledge about the cause of their injuries than that possessed by the doctors on whose advice they can reasonably rely.[30]

Ms. Wellington reported her symptoms to her doctor, seeking diagnosis and treatment, on at least three occasions, beginning in 2012 when her Essure device was inserted.[31] Her doctor did not identify Essure as the factual cause of her symptoms until 2015, when he ordered a pelvic ultrasound and discovered that one of the Essure coils was misplaced.[32] Defendants are misleading in their representations about Ms. Wellington's 2013 medical records, as her doctor questioned whether "? fibroids vs. Essure coils" were causing her persistent bleeding symptoms,

[29] Whether Plaintiffs had sufficient critical facts to put them on notice that they were injured and that injury was caused by another party's conduct cannot be viewed with the benefit of hindsight. At the relevant times here, Essure did not have a black box warning, did not have the subsequent restriction on its sale, and was still on the market in the United States.
[30] *Bohus*, 950 F. 2d at 929-30.
[31] PSMF Ex. 18, Wellington Decl. at ¶ 4, 5, 6.
[32] Wellington Decl. at ¶ 4, 5, 6, 7, 8.

reaching no conclusions, and advised her to consult another physician "about surgical options for management" and not, as Defendants write, surgical options for removing the device.[33]

With regard to Ms. Harvey, Defendants grossly mischaracterize the factual evidence in their Reply, suggesting that she did nothing to determine the cause of her symptoms from 2007 to 2014. This is simply untrue. Her declaration states that she consulted her primary care physician, gynecologist, a chiropractor, and a physical therapist about her symptoms in 2007; she underwent x-rays and diagnostic tests in 2007; she continued to consult with her primary care physician, gynecologist, and a chiropractor about her symptoms over the next few years; and she saw a physical therapist for treatment of pain from 2013-2016.[34] None of these medical professionals diagnosed Essure as the factual cause of her symptoms, or even recommended imaging to see if the Essure device was properly positioned.[35] The year 2014 is significant only because this is when Ms. Harvey began reading about other women having similar problems on the Essure Problems Facebook page, and specifically asking her doctors if her symptoms could be Essure related.[36] Finally, a doctor she consulted for a third opinion performed an HSG test in 2015, and discovered that her device appeared to be out of its proper placement.[37]

Ms. Thigpen suffered severe and persistent pain, but her doctors attributed her pain symptoms to other causes, such as cysts,[38] despite the temporal relationship between her Essure placement and her symptoms.

Unlike the women discussed above, Ms. Moxley put forth evidence that her pain symptoms (including severe and persistent pain and numbness in her arms, legs, and hands)

[33] Reply SMF, Ex. D at 3, 5.
[34] PSMF Ex. 8, Harvey Decl. at ¶ 6, 7, 8, 9, 10,
[35] Harvey Decl. at ¶ 10, 12, 17.
[36] Harvey Decl. at ¶ 12.
[37] Harvey Decl. at ¶ 13.
[38] PSMF Ex. 7, Thigpen Decl. at ¶ 8.

began in 2011, years after her Essure device was inserted (in 2007).[39] In addition to the lack of temporal relationship, she explained that because her pain and numbness was in her limbs and hands, and not in her pelvic region, it was impossible for her to connect her symptoms to Essure.[40] In addition, her doctors never advised her that those symptoms were caused by Essure.[41]

Plaintiffs have put forth sufficient evidence of reasonable diligence to create a genuine issue of material fact. They have set forth in their declarations evidence that they repeatedly brought their symptoms to the attention of their physicians, who failed to link their symptoms to Essure. Defendants' arguments that they were insufficiently diligent or could have taken certain actions earlier are for the jury to decide. Reasonable jurors could find that these exemplar Plaintiffs were not on notice of the factual cause of their injuries until their doctors identified Essure as the factual cause of their symptoms using imaging techniques years after their symptoms began.

Sufficiency of Notice of Causation in the Label: Thigpen, Moxley, Harvey, Wellington, Colding, Mattern, Ingram

Defendants also argue that the warnings in the "publicly available"[42] product label and "common sense"[43] were sufficient to put some of the exemplar Plaintiffs, including Ms. Thigpen, Ms. Moxley, Ms. Harvey, Ms. Wellington, and Ms. Colding[44] on notice that Essure was the cause of certain injuries. For example, the Reply argues that "Essure's labeling disclosed that

[39] PSMF Ex. 20, Moxley Decl. at ¶ 20.
[40] Moxley Decl. at ¶ 20,
[41] Moxley Decl. at ¶ 22.
[42] Reply at 19.
[43] Reply at 18.
[44] Defendants argue that the Essure label put Ms. Colding on notice of the injury caused by her right Essure coil (perforation of her bowel); they do not expressly make this argument about the injury caused by her left Essure coil (severe and persistent pain and other symptoms).

persistent pelvic, back, or abdominal pain was a risk of the device."[45] But if one examines the Patient Information Booklets available at the time these four women developed symptoms, the 2002 PIB states that "[v]ery few women reported persistent pain" (DSMF ¶ 6(i)), the 2006 Essure PIB states "[s]ome women in the clinical studies reported one or more episodes of pelvic, back, or abdominal pain" (DSMF ¶ 9(i), and the 2012 PIB states "you may experience mild to moderate pain" (DSMF ¶ 13(i)). A jury would need to determine whether reasonable diligence required the exemplar Plaintiffs to consult the label, and, if so, whether this labelling was sufficient to put a reasonably diligent woman on notice that her severe and persistent pain was caused by Essure or Bayer's conduct.

The same is true with regard to other women who Defendants argue should have known Essure was the factual cause of their injuries based upon warnings in the product label (such as Ms. Mattern, whose left coil perforated and migrated outside her fallopian tube, or Ms. Ingram and Ms. Stegall, who were diagnosed with nickel allergies.[46]) It is for the jury to determine whether a reasonably diligent individual in each Plaintiff's circumstances would have reviewed the product label, and if so, whether the information in the label was sufficient to put them on notice of the factual cause of their particular injuries.

In the *In re Prempro Products Liability Litigation*, the Eighth Circuit heard an appeal of a jury decision regarding injuries caused by hormone replacement therapy (HRT).[47] One of the issues the defendants appealed concerned the timeliness of the complaint. The defendants argued that the plaintiff should have known, based on label information about the risk of breast cancer, that her breast cancer was HRT-related at the time she was diagnosed with breast cancer in 2000.

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[45] Reply at 18.
[46] Ms. Stegall was diagnosed with a nickel allergy, but never told that Essure contained nickel. PSMF Ex. 11, Stegall Decl. at ¶ 16. Ms. Ingram was told by an allergist that, despite her nickel allergy, he did not think that the nickel in Essure was the cause of her problems. PSMF Ex. 13, Ingram Decl. at ¶ 10.
[47] *In re Prempro Products Liability Litigation,* 586 F. 3d 547 (8th Cir. 2009).

The plaintiff argued that she did not learn of the connection until the Women's Health Initiative (WHI) study was published and publicized in 2002, and thus, pursuant to the discovery rule, the cause of action accrued only after publication of the WHI study. The defendants responded that the WHI study provided no new information. The Eighth Circuit disagreed, citing the plaintiff's evidence that there had been: 1) a change in the label after the publication of the WHI findings, devoting substantial label space to the results; 2) widespread coverage of the results of the study in the mainstream media; and 3) a steep drop in sales of HRT after the WHI study was published, "suggesting that the WHI study did more than affirm that which was already known."[48]

Plaintiffs in the present cases have put forth evidence that their own doctors did not tell them that their injuries were Essure related, as well as evidence that: 1) the FDA ordered significant label changes in 2016 (with the addition of a black box warning), and the FDA ordered a significant procedural change for patient acknowledgment of the risks of Essure in 2018, to address the fact that doctors and patients were still not being adequately warned of the risks associated with the Essure device after the 2016 label change; 2) the 2018 FDA ruling, in particular, received widespread media coverage, as did Bayer's subsequent decision to remove Essure from the market;[49] and 3) there was a steep drop in sales subsequent to the 2016 label change and the 2018 change in the procedure for advising patients of the risks.

In addition, there was a paucity of scientific literature on causation and risk at the time the exemplar Plaintiffs suffered their injuries. In fact, in February 2016, the FDA "ordered Bayer, the company that manufactures Essure, to conduct a new postmarket surveillance study designed *to provide important information about the risks of the device in a real-world*

[48] *Id.* at 564.

[49] While all of the Plaintiffs who are the subject of Defendants' present motion filed their cases prior to the 2018 FDA decision, there are likely to be significant number of plaintiffs in this litigation who could not have learned, prior to hearing the publicity surrounding the 2018 decisions of the FDA and Bayer, that their injuries were Essure related.

environment. Bayer will be required to develop and conduct a post-market study that will provide data *to help the agency to better understand* the risks associated with Essure and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure device. The study will also evaluate how much these complications affect a patient's quality of life….The *FDA will use the results of this study to determine what, if any, further actions related to Essure are needed to protect public health."*[50]

Finally, it is important to note that Bayer has continued to downplay the risks of Essure and the evidence of a causal connection between the device and women's symptoms. For example, at the 2015 FDA hearing, Bayer's Vice President of U.S. Medical Affairs, Dr. Zampaglione testified that "there are so many different etiologies. . . is this due to the inserts or potentially due to something else?"[51] and also "So Essure research spans over a decade. We have data on over 10,000 women. That data affirms that the safety and efficacy of Essure is consistent across all data points, clinical trials, independent literature, and post-marketing surveillance."[52] Even in 2018, while Defendants' Motion for Partial Summary Judgment was pending, in which they argued that lay women were or should have been aware that Essure was the factual cause of their injuries at the time they arose, Dr. Zampaglione was quoted on a CBS News segment saying that it was "hard to say" whether adverse events were caused by Essure because "a lot of those symptoms can be hormonally-related and common as women go through reproductive life."[53]

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[50] FDA News Release, FDA takes additional action to better understand safety of Essure, inform patients of potential risks, February 29, 2016 (emphasis added). See Attachment B. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm

[51] PSMF Ex. 34, 2015 FDA Hearing Transcript at pp. 204-205.

[52] PSMF Ex. 34, 2015 FDA Hearing Transcript at p. 37.

[53] PSMF Ex. 35, CBS News Report dated May 21, 2018.

With all of this evidence, a reasonable jury could find that the Essure label was insufficient to put Plaintiffs on notice of the cause of their injuries at the time the injuries occurred.

Even If Women Suspect Their Injuries May Be Essure Related, This Only Triggers the Duty of Inquiry. Credibility, Diligence, and Other Factual Issues Go To The Jury (Ingram, Stegall, Bridwell)

Defendants argue that Ms. Ingram, Ms. Stegall, and Ms. Bridwell suspected their injuries were caused by Essure more than two years prior to filing suit. But while an *unrebutted* suspicion may be sufficient to start the clock, each of these women has put forth evidence that her suspicions were *rebutted* by their treating doctors. Thus, there are issues of fact for the jury.

Defendants specifically challenge Ms. Ingram's credibility, arguing that her declaration is self-serving. It is for a jury, not the Court, to decide whether Ms. Ingram's recitation of the facts is credible. Similarly, it is for a jury to decide whether a reasonably diligent person in Ms. Ingram's position would have obtained a copy of her medical records.

Plaintiffs have put forth evidence that these three women *were* diligent in seeking out medical opinions regarding their symptoms and the cause of those symptoms, seeing multiple doctors and undergoing multiple diagnostic tests, but no doctor told them that Essure was the factual cause of their symptoms. It is for a jury to decide whether it was reasonable for these three women to rely upon the reassurances of their physicians that their symptoms were not Essure related, which rebutted their suspicions to the contrary. It is for the jury to decide whether all three women were sufficiently diligent in their efforts to learn the factual cause of their injuries, given their personal suspicions that their symptoms were Essure related. It would be improper for the Court to make such findings, and without making such findings, the Court cannot grant summary judgment.

II. As Set Forth in the Rule 56(d) Affidavit, Plaintiffs Need Discovery Relevant to the Fraudulent Concealment Doctrine Before They Can Brief that Issue in a Supplemental Response to Defendants' Motion for Partial Summary Judgment

Understanding that Plaintiffs were faced with a Motion for Partial Summary Judgment before they had received any meaningful discovery from Defendants, the Court issued an order instructing the Plaintiffs to respond to Defendants' Motion *or* file a Rule 56(d) affidavit seeking additional discovery. Although the Plaintiffs required discovery in order to argue that the statute of limitations was tolled by the equitable doctrine of fraudulent concealment, Plaintiffs had sufficient evidence to argue that the statute of limitations on their tort claims was tolled by the discovery rule. Because Plaintiffs share the Court's desire to see this litigation progress, Plaintiffs decided to respond to Defendants' Motion with respect to their discovery rule argument by the date set by the Court but sought the opportunity to take additional discovery on the fraudulent concealment doctrine should the Court find in Defendants' favor with regard to the discovery rule.[54]

Defendants argue that Plaintiffs have not created a genuine issue of material fact as to fraudulent concealment, but Plaintiffs believe they made it clear that they were not responding to the Motion on this issue, but were only seeking the discovery they need to support this theory of equitable tolling. Once the targeted discovery requested in the Affidavit is obtained, Plaintiffs' evidence and argument can be set forth in a supplemental response. The evidence of fraud or

[54] As noted above, Plaintiffs do not read the Motion as seeking summary judgment on Plaintiffs' breach of warranty claims. However, should the Court disagree, the Plaintiffs would require the discovery on fraudulent concealment requested in the Rule 56(d) affidavit to formulate a response as to this cause of action. An action for breach of warranty generally must be brought within four years after the breach of the warranty occurs. *Cucchi v. Rollins Protective Services, Co.*, 574 A.2d 565, 572 (Pa. 1990). Usually, a breach of warranty occurs when delivery of the warranted product is made, but when a warranty explicitly extends to future performance, and discovery of the breach must await the time of such performance, the cause of action accrues when the breach is or should have been discovered. *Id.* The discovery rule does not otherwise apply to breach of warranty claims. However, if plaintiffs can prove that defendants engaged in *fraudulent concealment*, causing plaintiff to deviate from her inquiry as to whether a warranty has been breached, the statute of limitations on breach of warranty claims may be equitably tolled. *Speicher v. Dalkon Shield Claimants Trust*, 943 F.Supp. 544, 558 (E.D. Pa. 1996). Therefore, Plaintiffs may also require discovery on the doctrine of fraudulent concealment, with regard to certain injuries, should the Court interpret Defendants' Motion as encompassing the breach of warranty claims.

concealment set forth in Plaintiffs' initial Response was only put before the Court to demonstrate that Plaintiffs are not on a fishing expedition, but have reason to believe that they will find relevant discovery which supports equitable tolling.

Defendants take the position that further discovery on the issue of fraudulent concealment would not advance Plaintiffs' argument, stating that: "fraudulent concealment cannot toll the limitations period when plaintiffs could have discovered the cause of their injuries with reasonable diligence."[55] This exhibits a clear misunderstanding of the fraudulent concealment doctrine. In *Oshiver*, the Third Circuit distinguished the key issues for the fraudulent concealment doctrine from the key issues for the discovery rule, noting that while the "discovery rule keys on a plaintiff's cognizance, or imputed cognizance, of *actual injury*…Equitable tolling, on the other hand, keys on a plaintiff's cognizance, or imputed cognizance, of *facts supporting the plaintiff's cause of action."*[56] The Third Circuit held that "where Defendant actively misleads plaintiff…statute of limitations will not begin to run…until facts *which would support plaintiff's cause of action* are apparent."[57]

This doctrine focuses on *actions the Defendants took* which caused Plaintiffs to relax their vigilance as to Defendants' potential liability for their injuries, and much of the evidence of these actions is fully within Defendants' control. In *Hoppe*, the Eastern District of Pennsylvania held:

> *Any inquiry into defendants' alleged fraudulent concealment would be premature at this stage, given that the factual record is completely undeveloped.*
>
> Pennsylvania law directs a court to leave material factual issues regarding tolling for the jury. See, e.g., *Fine*, 870 A.2d at 860 (reversing lower court's grant of summary judgment where there was conflicting deposition testimony as to whether defendant had disclosed the risk of injury prior to surgery).

[55] Reply at p. 28.
[56] *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1390 (3d Cir. 1994) (emphasis added).
[57] *Id.*

> In cases involving tolling due to allegations of fraudulent concealment, the Third Circuit has encouraged and approved of allowing the factual record to be sufficiently developed before reaching the issue. See, e.g., *Byrnes v. De Bolt Transfer, Inc.*, 741 F.2d 620, 626-27 (3d Cir. 1984) (remanding to the lower court to "spell[] out in greater detail" its conclusions regarding fraudulent concealment and to "make whatever additional factual findings it deems necessary to the disposition of the tolling issue"); *Urland v. Merrell-Dow Pharmaceuticals, Inc.*, 822 F.2d 1268, 1276-77 (3d Cir. 1987) ("We stress that in this case, the district court did not decide in favor of [defendant's] statute of limitations defense on a pre-trial motion. Instead, the issue was fairly presented to a jury, which decided the relevant factual question adversely to the [plaintiffs].")
>
> *Following the cues laid by state and federal precedent, I will allow further development of the record underlying plaintiff's allegations of fraudulent concealment in order to accurately determine whether there is a triable issue.* As plaintiff avers in his supporting affidavit, discovery is necessary in order to allow him to uncover relevant information solely in the defendant's control. Issues that must be fleshed out include: the date and extent of defendants' alleged knowledge of Paxil's risk of suicidality; the scope of defendants' duty to disclose the risk and its efforts, if any, to do so; and its communications, if any, with Mrs. Hoppe or her doctor or others similarly situated. Until the record is further developed as to these issues, it is impossible to tell whether the question of fraudulent concealment lies with judge or jury. Therefore, I deny defendants' motion for summary judgment as to plaintiff's wrongful death and survival tort actions and allow the case to proceed to discovery.[58]

Similar issues need to be fleshed out in this case, before exemplar Plaintiffs can set forth evidence of their reliance on Defendants' acts of concealment and brief the issue of fraudulent concealment. Courts have consistently held that it is improper to decide fraudulent concealment without a developed factual record.[59]

Consistent with the federal rules, this Court's order, and applicable case law, Plaintiffs filed a 56(d) affidavit outlining the discovery they need to develop the record regarding the fraudulent concealment doctrine. Plaintiffs stated: "Plaintiffs have yet to engage in any

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[58] *Hoppe v. Smithkline Beecham Corp*., 437 F. Supp. 2d 331 (E.D. Pa. 2006); citing to *Fine*, 870 A.2d 850, 860 (Pa. 2005); *Byrnes v. De Bolt Transfer, Inc*., 741 F.2d 620, 626-27 (3d Cir. 1984) (remanding to the lower court to "spell[] out in greater detail" its conclusions regarding fraudulent concealment and to "make whatever additional factual findings it deems necessary to the disposition of the tolling issue"); *Urland v. Merrell-Dow Pharmaceuticals, Inc.*, 822 F.2d 1268, 1276-77 (3d Cir. 1987).

[59] *Id.*

significant discovery and have not had any opportunity to take any depositions as it relates to the issues of the doctrine of fraudulent concealment and equitable estoppel." Plaintiffs explained that an ESI order had not been entered, and Bayer had not yet responded to discovery requests served over one year ago. Plaintiffs sought several corporate representative depositions which "would allow Plaintiffs to inquire as to when the concealment began, how long it lasted, the scope of the concealment…and why Essure has been pulled off of the market in every country except the United States." Plaintiffs filed their 56(d) affidavit to show that there is not a complete factual record on this issue, and to request targeted discovery. Pursuant to the Third Circuit's holdings, a 56(d) affidavit which contains the above should be granted "almost as a matter of course."[60]

Lastly, Defendants' Reply argues that Plaintiffs failed to adequately allege fraudulent concealment in their Complaints. Plaintiffs are not required to anticipate affirmative defenses (such as the statute of limitations) when setting forth allegations in their Complaints.[61] However, in this litigation, Plaintiffs' complaints each contain sections entitled "Summary of Active Concealment" "Fraudulent Concealment" and "Equitable Estoppel," which outline some of the acts and omissions which constituted the same, including the following:[62]

- Defendant's **failure to report, document, or follow up on the known adverse event complaints, and concealment and altering of adverse events**, serious increased risks, dangers and complications, constitutes fraudulent concealment that tolls the Plaintiffs' statute of limitations.

- Defendant also is estopped from relying on any statute of limitations defense because they continued to refute and deny reports and studies questioning the safety of Essure®, **actively and intentionally concealed the defects and adverse events**, **suppressed reports and adverse information, sponsored and paid for studies which falsely characterized the risks and benefits of Essure®, and failed to disclose known dangerous defects and serious increased risks and complications** to the FDA, physicians and Plaintiffs. As a result of Defendant's concealment of the true character, quality, history, and

[60] *Sames v. Gables*, 732 F.2d 49, 51 (3d Cir. 1984).
[61] *Hoppe*, 437 F. Supp. 2d at FN 5.
[62] Complaint ¶¶ 102-143.

nature of their product, it is estopped from relying on any statute of limitations defense.

- Actively and intentionally concealed from Plaintiffs that their physicians were not trained pursuant to FDA-approved training.

- Actively and intentionally concealed from Plaintiffs and Plaintiffs' physicians' risks **by making the misrepresentations/warranties discussed herein knowing they were false**. In short, Defendant knew the misrepresentations were false because they had studies and reports which showed the opposite, yet altered and concealed the same from Plaintiffs, the FDA and Plaintiffs' physicians. **Defendant made the misrepresentations with the intent of misleading Plaintiffs into relying on them because they had studies and reports which showed the opposite, yet decided to conceal the same** (collectively "the acts and omissions").

- Defendant committed affirmative independent acts of concealment (including the acts and omissions) and intentionally mislead Plaintiffs as noted above upon which Plaintiffs and Plaintiffs' physicians relied on.

- Defendant also prevented Plaintiffs from asserting their rights by committing affirmative independent acts of concealment as noted above upon which Plaintiffs relied.

Because Bayer's argument that "additional discovery would not change this reality and cannot change the outcome of this motion"[63] fails, Plaintiffs respectfully ask the Court to grant the Rule 56(d) motion for targeted discovery if it is necessary for the Court to reach this issue.

III. Conclusion

On a motion for summary judgment, the moving party bears the initial burden of informing the Court of the bases for the motion, and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact.[64] As noted above, although Defendants' motion is captioned a motion for *partial* summary judgment, it is not at all clear to which causes of action and to which injuries it was intended to apply. Defendants have left Plaintiffs (and the Court) in the dark as to the precise bases of Defendants' Motion. In fact, this

[63] Reply at p. 31.
[64] *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Wawrzynek v. Statprobe, Inc.*, 2007 U.S. Dist. LEXIS 80155.

very issue was raised by the Court in chambers[65] and Defendants have done nothing to remedy the Court's concerns. Defendants have failed to identify the bases of the motion and their Motion for Partial Summary Judgment should be denied for failing to meet their burden.

Where the moving party satisfies their initial burden, the non-moving party must come forward with evidence showing that a genuine factual issue exists. If there is a genuine factual dispute as to when a plaintiff was able, with the exercise of reasonable diligence, to discover the factual cause of her injury (or injuries), a jury must decide those factual issues. Each of the exemplar Plaintiffs has set forth sufficient evidence to create a genuine issue of material fact as to whether her conduct was reasonably diligent and when she was able to discover that Essure was the factual cause of her injuries. Thus, each woman has met her burden of creating a genuine issue of material fact as to whether the discovery rule tolls the statute of limitations on her tort claims. Accordingly, the Motion for Partial Summary Judgment should be denied.

Dated: August 29, 2018.

Respectfully submitted,

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[65] This Court asked Defendants if its Motion covered all claims and Defendants advised that it did cover all claims. However, as noted above, there is no discussion in their Motion or their Reply of the statute of limitations applicable to Plaintiffs' breach of warranty claims.

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CERTIFICATE OF SERVICE

I, hereby certify that on August 29, 2018, the foregoing was filed via the Court's CM/ECF system, which will automatically serve and send notification of such filing to all registered attorneys of record.

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